UNITED STATES OF AMERICA BEFORE THE FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of

ECUMED HEALTH GROUP

a corporation,

and

AMADOR REYES,
JUAN C. CARRAI,
RICHARD W.STONE, M.D.,
and ERLINDA E. ENRIQUEZ, M.D.
individuals

ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY

FDA Docket: 2004H-0322

ORDER

By Motion dated August 17, 2004, Respondents, Ecumed Health Group and Amador Reyes request a 30 days extension of the time to file their answers to the complaint in this proceding pursuant to 21 C.F.R. §17.9(c). Respondents indicate that Counsel for the Complainant, the Center for Devices and Radiological Health, has no objection to the extension of time. Accordingly the motion will be granted.

It is ORDERED, that the time for filing answers by Respondents Ecumed Health Group and Amador Reyes is extended so as to require said filing(s) on or before September 17, 2004.

It is further ORDERED, that pursuant to the authority set forth in 21 C.F.R. § 17.19(b)(17), the following procedural requirements will be in effect during the course of the hearing:

- 1. The hearing will be held utilizing written direct evidence with oral cross-examination, if necessary.
- 2. 21 C.F.R. § 17.25 is modified to require the submission of all written evidence and testimony to the Dockets Management Branch with copies to this office and the other participants or their counsel.
- 3.21 C.F.R. § 17.30(c) is modified to require that all due dates be construed as the date by which filings or

exchanges are to be <u>received</u>. This requirement may be met (1) by depositing the filing in overnight mail on the day before the due date or (2) by FAX, with the hard copy mailed at the same time.

- 4. Requests for extensions of time must be submitted in writing at least five full working days before the due date. However, unopposed requests for extensions of time may be made at any time up to and including the day prior to the due date.
- 5. 21 C.F.R. § 17.31(a) is modified to provide for the submission of an original and <u>only one</u> copy, and that all documentary evidence, including written direct testimony, be submitted in exhibit form numbered in sequence with a letter prefix, i.e., Exhibit No. G-1, G-2, etc., for Complainant's exhibits, and Exhibit No. R-1, R-2, etc., for Respondents' exhibits.
- 6. 21 C.F.R. § 17.32 is modified to require that written motions and responses thereto include a draft order.*
- 7. All documentary submissions will be received into evidence subject to motions to strike.

Dated this $\frac{10^{12}}{2}$ day of August, 2004.

/s/Daniel J. Davidson
Daniel J. Davidson
Administrative Law Judge
U.S. Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

^{*} All draft orders should also be sent by e-mail to the office of the Administrative Law Judge in Microsoft word format.